K052994

JMP-2005-014

MAR 2 2 2006

Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

Submitted by:

Jennifer M. Paine
Manager, Regulatory Affairs
Ethicon, Inc., A *Johnson & Johnson* Company
Route 22 West, PO Box 151
Somerville, NJ 08876

Name/Classification of Device:

Class II in 21 CFR § 880.5725 (MEB) and 21 CFR § 868.5120 (BSO)

Trade Name:

SEMPERFLO Infusion System

Predicate Devices:

On-Q Pain Pump (I-Flow Corp)
VICRYL* Suture
BAXTER Pain Management System

Statement of Intended Use:

The SEMPERFLO Infusion System is intended to provide continuous percutaneous infusion of prescribed solutions at a pre-set rate.

The device is intended for intraoperative placement in hospital or alternate medical site environments. Once implanted, the device and pump may be used in homecare settings.

The device is not intended for intravascular, intrathecal, or epidural use, nor is it indicated for use with blood, blood products, lipids or fat emulsions.

When packaged in the kit configuration for pain management (to be known as the SEMPERFLO* Pain Management System), the intended use will be as follows:

> The SEMPERFLO Pain Management System is intended to provide continuous percutaneous infusion of prescribed solutions at a pre-set rate for post-operative pain management.
>
> The SEMPERFLO Pain Management System is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or in close proximity to nerves when compared with narcotic only pain management.

Device Description:

The proposed device consists of a single-use disposable elastomeric infusion pump, designed to deliver medication/fluids at a constant flow rate, and a microcatheter for fluid delivery. The device is intended for use in tissue, and is not intended for use in intravascular, epidural or intrathecal modes of delivery. Delivery of medication is achieved via an elastomeric reservoir that maintains relatively constant pressure, forcing solution through a 0.2μ filter and into the associated microcatheter assembly. The device will be provided as a convenience kit.

Summary of Technological Characteristics of New Device to Predicate Devices:

The modified device has similar technological characteristics as the predicate devices. Like currently marketed devices, it is a kit providing a sterile infusion system. The proposed device uses the same or similar materials as those used in other currently marketed implantable or non-implantable medical devices. The mechanism of action is the same as for predicate devices.

Performance Data:

Biological reactivity of the materials has been assessed using methods specified in ISO Standard 10993-1, and the material was found to be acceptable for its intended use. Results of functional performance testing (bench and animal testing) have been submitted. These results indicate that the proposed device meets or exceeds all functional requirements.

Conclusions:

Based on the similarities to the predicate devices identified in this submission, we conclude that the modified device is substantially equivalent to the predicate devices under the Federal Food, Drug, and Cosmetic Act.

*Trademark of Ethicon, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2006

Ms. Jennifer M. Paine
Ethicon, Incorporated
Route 22 West
P.O. Box 151
Somerville, New Jersey 08876

Re: K052999
Trade/Device Name: SEMPERFLO Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: II
Product Code: MEB
Dated: February 27, 2006
Received: February 28, 2006

Dear Ms. Paine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052999

Device Name: SEMPERFLO Infusion System

Indications for Use:
The SEMPERFLO Infusion System is intended to provide continuous percutaneous infusion of prescribed solutions at a pre-set rate.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible], General Hospital
[illegible] Dental Devices